

JAN - 8 2004

510(k) Summary of safety and effectiveness

Applicant: asap endoscopic products GmbH
Tullastr. 87 a
79108 Freiburg / Germany

Name of contact: Dr. Martina Guenderoth
Regulatory Affairs Manager
C.R.C. Partnerschaftsgesellschaft
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Device name: Sinuscope, Types:
10-0036-00, 10-0037-00, 10-0038-00, 10-0039-00,
10-0040-00, 10-0041-00, 10-0042-00, 10-0043-00,
10-0044-00, 10-0045-00, 10-0046-00, 10-0086-00,
10-0047-00

Common name: Sinuscope

Predicate device name: Sinuscope (K 981751)

Classification name: Nasopharyngoscope (flexible or rigid); 77-EOB

Code of Federal Regulations (CFR) number: 21 CFR 874.4760

General device description

The *asap ENT endoscope* is of the rigid type with a new generation of compact objectives and a newly developed rod-lens system.

The basic design of the *asap ENT endoscope* is similar to those legally available for sale in the U.S.A.. It consists of an eyepiece and the body with light guide and rod-lens system. The body is designed of an outer and an inner tube of surgical steel. The light carrying fibers are sandwiched between these tubes. The inner tube of the body contains the rod-lens system.

Indications for use

The *asap ENT endoscope* is intended to provide the physician with a means for direct viewing of the nasal cavity and nasal pharynx by providing illumination and visualization of these regions during various diagnostic and therapeutic procedures.

The *asap ENT endoscope* is reusable.

Voluntary standard compliance

The *asap ENT endoscope* complies with

- applicable portions of voluntary standards IEC 60601-2-18
- DIN 58105, part 1 and 2
- DIN 17442 (medical steel), as well as applicable portions of
- DIN 980

Substantially equivalence - Safety and effectiveness

The specifications and intended use of the *asap ENT endoscope* are the same to those of the claimed predicate devices. There are no significant differences between the *asap ENT endoscope* and the claimed predicates in design or conditions of intended use.

The *asap ENT endoscope* is constructed of materials of the same specifications as the predicate devices to ensure biocompatibility. The *asap ENT endoscope* conforms to applicable ISO standards.

The device will be sold non-sterile, to be sterilized prior to each procedure by the user. The ability to repeatedly adequately sterilize the devices has been confirmed by validation protocol.

Conclusion

In all respects, the *asap ENT endoscope* is substantially equivalent to one or more rigid endoscopes currently marketed in the USA.

It is constructed of materials of the same specifications as the predicate devices to ensure biocompatibility and it conforms to applicable ISO standards.

The ability to repeatedly adequately sterilize the *asap ENT endoscope* has been confirmed by validation protocol.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

JAN - 8 2004

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Asap Endoscopic Products GmbH
c/o Martina Guenderoth
Regulatory Affairs Manager
C.R.C. Partnerschaftsgesellschaft
Katharinenstr.5
23554 Lubeck, Germany

Re: K032822
Trade/Device Name: Asap ENT Endoscope
Regulatory Class: Class II
Product Code: EOB
Dated: August 21, 2003
Received: September 10, 2003

Dear Dr. Guenderoth:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4613. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "A. Ralph Rosenthal". The signature is fluid and cursive, with the first name "A." and last name "Rosenthal" clearly distinguishable.

A. Ralph Rosenthal, M.D.

Director

Division of Ophthalmic and Ear,

Nose and Throat Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K032822

Device Name: asap ENT endoscopes

Indications For Use:

The *asap ENT endoscope* is intended to provide the physician with a means for direct viewing of the nasal cavity and nasal pharynx by providing illumination and visualization of these regions during various diagnostic and therapeutic procedures.

The *asap ENT endoscope* is reusable.

Prescription Use ☒ YES
(Part 21 CFR 801 Subpart D)

AND/OR


Over-The-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page 1 of _____

ption Use ☒
(21 CFR 801.109)


(Division Sign-Off)
Division of Ophthalmic Ear,
Nose and Throat Devices

510(k) Number K032822